Confidential
Phone: 305-254-6793 Stratus Pharmaceutical Inc. FAX: 305-254-0199
12379 SW 130th Street
Miami, FL 33186
ahoyo@bellsouth.net

AUG 19 2011

"510(k)" Premarket Notification: K110172, SONAFINE® Wound Dressing

510(k) Summary

Summary Information:

- Submitters Name and Address: Stratus Pharmaceutical
  12379 SW 130th Street
  Miami, Florida 33186

- Contact Person: Alberto Hoyo
  President
  Phone: 305-254-6793
  E-Mail: ahoyo@bellsouth.net

- User Fee ID Number: MD 6051830-956733

- Date of Summary Preparation: September 30, 2010

- Name of Device:
  - Proprietary: SONAFINE® Wound Dressing
  - Common: Dressing Wound and Burn Hydrogel w/Drug or Biologic
  - Classification Name: Dressing Wound and Burn Hydrogel w/Drug or Biologic

- Medical Device Classification: Unclassified

- Product Code: MGQ

- Identification of predicate devices to which substantial equivalence is being claimed:

o MimyX™ Cream	Stiefel Laboratories	K041342
o BIAFINE® Wound Dressing Emulsion	Medix Pharma	K964240
o PruMyx™ Cream	PruGen Inc.	K082089

- Description of the Device: SONAFINE® Wound Dressing is a preserved emulsion intended to be used as a topically applied preparation to breached and intact skin and

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is provided in a patient ready, 28 gram (one (1) ounce), 45 gram and 90 gram collapsible tube.

- Intended use of the Device: SONAFINE® Wound dressing provides a moist wound environment. SONAFINE® Wound Dressing is useful in the management of full and partial thickness wounds including dermal ulcers, leg ulcers, superficial wounds, first and second degree burns and donor sites.
    - As a prescription product a physician is needed to diagnose the disease condition and is indicated for the management and relief of the burning and itching associated with various types of dermatosis, including atopic dermatosis, allergic contact dermatitis and radiation dermatitis.
    - As an OTC product the product is indicated for the management of minor cuts, minor burns, and minor lacerations.

- Technology Characteristics: This particular, preserved, formulation does not affect the intended use or alter the fundamental scientific technology of the device.

- Non-Clinical Performance Data: SONAFINE® Wound Dressing has been evaluated in accordance with Part 10-993 of the International Standard Organization (ISO). Standard tests which include:

    - Agar Overlay (direct contact) Cytotoxicity testing (Exhibit II) indicated a grade 0 cytotoxic grade.
    - ISO Intracutaneous reactivity (Irritation) testing indicates a non-irritant (Exhibit III).
    - Repeat Patch Dermal Sensitization Test (Buehler Method) indicates the product is a non-sensitizer (Exhibit IV).
    - Stability has been demonstrated over a three (3) month period at Room Temperature and accelerated conditions and was found to maintain the products attributes and characteristics.

SONAFINE® Wound Dressing has not been studied in a clinical setting.

End of Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stratus Pharmaceutical
% Mr. Alberto Hoyo
Presiodent
12379 SW 130th Street
Miami, Florida 33186

AUG 19 2011

Re: K110172
Trade/Device Name: SONAFINE® Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 1, 2011
Received: August 2, 2011

Dear Mr. Hoyo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

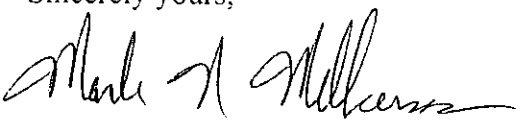
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number: K110172

Device Name: SONAFINE® Wound Dressing

Indications for Rx Use:

- SONAFINE® Wound Dressing is indicated for topical use in the management of full and partial thickness wounds including dermal ulcers, leg ulcers, superficial wounds, first and second degree burns and donor sites to include:

- Radiation Dermatitis
- Various types of dermatoses
- Atopic dermatitis
- Allergic contact dermatitis
- Dry waxy skin

SONAFINE® Wound Dressing maintains a moist wound and skin environment.

Indications for OTC use:

SONAFINE® Wound Dressing is indicated for the management of minor cuts, minor burns, and minor lacerations.

SONAFINE® Wound Dressing maintains a moist wound and skin environment.

Contraindications:

- Contraindicated for individuals with a known sensitivity to the components contained in the formulation

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

David Krueger for MSW
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110172